510(k) Summary

Company Ethicon Endo-Surgery, LLC
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Date Prepared January 15, 2007

Device Name Trade Name: InScope™ Tissue Apposition System
Common or Usual Name: Tissue Apposition System

Classification Name:
Endoscope and Accessories [21CFR 876.1500 (OCW, MXW, GAW)]

Predicate Device Bard® EndoCinch™ Suturing System (K003956)
LSI Solutions Flexible Suture Placement Device and Acc (K011016)
Ethicon Endo-Surgery® Endoscopic Suturing System (K061770)
EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system (K062875)

Device Description
The InScope™ Tissue Apposition System is a sterile, single patient use disposable suture system for approximating and securing soft tissue within the gastrointestinal tract. It is intended to perform suturing in conjunction with endoscopes having a working channel of 2.8 mm or larger.

There are four essential devices, and two secondary components:

1. Tissue Anchor Applier
2. Tissue Anchor with suture
   a. Tissue Anchor Loader
3. Knotting Element Applier
4. Knotting Element
   a. Knotting Element Loader

The InScope™ Tissue Anchor Applier is used to place and anchor sutures in the tissue of the GI tract. Suture position is maintained via a metal tissue anchor structure attached to the distal end of each suture strand. Following suture placement, the Knotting Element Applier is advanced over the trailing ends of the anchored sutures and advanced distally. After the sutures are properly tensioned to appose tissue, the Knotting Element is deployed to secure the suture and cut the trailing ends. The Tissue Apposition System can be used to treat a variety of defects endoscopically, including ulcers and perforations.

Indications for Use The InScope™ Tissue Apposition System is indicated for endoscopic placement of suture(s) and approximation of soft tissue.

Technological Characteristics The InScope™ Tissue Apposition System is similar in design to the Bard® EndoCinch™ and Ethicon Endo-Surgery® Endoscopic Suturing System predicate devices, as both devices provide an endoscopic means of suture termination. The new device is different from these predicates devices as it does not attach externally to an endoscope, but is advanced down the working channel of the endoscope.

Performance Data Bench and animal testing was performed to demonstrate the new device performs as intended. Bench testing demonstrated the holding strength of the InScope™ Knotting Element component is substantially equivalent to the Bard® EndoCinch™ suture anchor, and that the anchor attachment force meets the USP requirement. Testing in the porcine animal model demonstrated successful closure of colonic and gastric perforations, with normal results for the healing process.

Each material in the InScope™ Tissue Apposition System was assessed for biocompatibility using ISO 10993-1: "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing" and FDA General Program Memorandum #G95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing." and each was found to be biocompatible. Biocompatibility for both limited patient contacting and permanent patient contacting/implant materials has been established through history of use in other marketed Ethicon Endo-Surgery medical devices and biocompatibility test results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Ms. Kimberly Shoemaker, RAC
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4545 Creek Road
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Re: K070151
Trade/Device Name: InScope™ Tissue Apposition System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW, MXW, GAW
Dated: July 10, 2007
Received: July 11, 2007

Dear Ms. Shoemaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

8/13/07

Enclosure

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Indications for Use

510(k) Number (if known): K070151

Device Name: **InScope™ Tissue Apposition System**

Indications for Use:

The Tissue Apposition System (TAS) is indicated for endoscopic placement of suture(s) and approximation of soft tissue.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070151